PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06 — A1

(11) International Publication Number: **WO 96/31174**

(43) International Publication Date: 10 October 1996 (10.10.96)

(21) International Application Number: PCT/US96/04744

(22) International Filing Date: 5 April 1996 (05.04.96)

(30) Priority Data:
08/417,385 5 April 1995 (05.04.95) US

(71) Applicant: SCIMED LIFE SYSTEMS INC. [US/US]; One Scimed Place, Maple Grove, MN 55311-1566 (US).

(72) Inventor: DEL TORO, Connie; 2165 H Shenandoah Court, Plymouth, MN 55447 (US).

(74) Agents: ANDERSON, William, E., II et al.; Vidas Arrett & Steinkraus, Suite 1540, 920 Second Avenue South, Minneapolis, MN 55402-4014 (US).

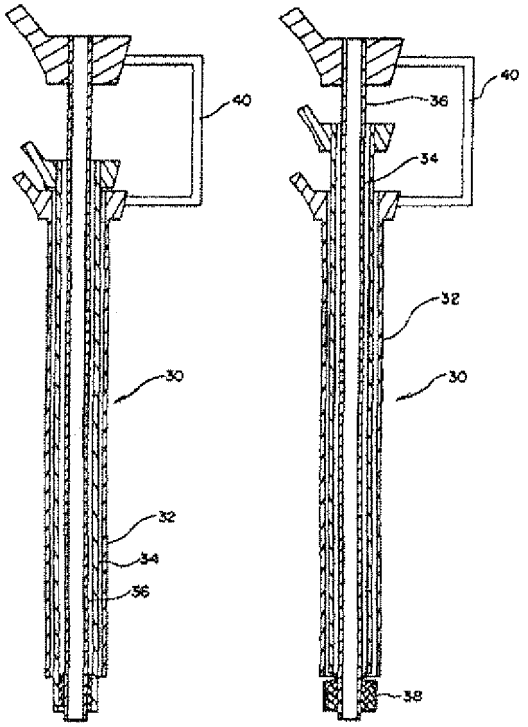
(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: PULL BACK STENT DELIVERY SYSTEM

(57) Abstract

A delivery system (30) for implantation of a medical device in a vessel which has three concentric shafts (32, 34, 36), an inner shaft (36) for carrying a medical device (38), a middle pull back shaft (34) and an outer stiffening shaft (32). The inner and outer shafts are connected together at the proximal end (40) of the delivery system to preclude the inner shaft from moving axially relative to the outer shaft as the middle pull back shaft is retracted. This allows for accurate placement of the medical device.



B3

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgystan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic			SE	Sweden
CG	Congo	KR	Republic of Korea	SG	Singapore
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LR	Liberia	SZ	Swaziland
CS	Czechoslovakia	LT	Lithuania	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	LV	Latvia	TJ	Tajikistan
DK	Denmark	MC	Monaco	TT	Trinidad and Tobago
EE	Estonia	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	UG	Uganda
FI	Finland	ML	Mali	US	United States of America
FR	France	MN	Mongolia	UZ	Uzbekistan
GA	Gabon	MR	Mauritania	VN	Viet Nam

Pull Back Stent Delivery System

Background of the Invention

1. Field of the Invention

The present invention relates to an improved delivery system for delivering and deploying a medical device, such as a stent. More specifically, the invention relates to a delivery system for more accurate placement of a medical device such as a stent when using a pull back delivery system.

2. Description of the Related Art

Stents and delivery systems for deploying stents are highly developed and well known field of medical technology. Stents have many well known uses and applications. A stent is a prosthesis which is generally tubular and which is expanded radially in a vessel or lumen to maintain its patency. Stents are widely used in body vessels, body canals, ducts or other body lumens.

Stents, stent-grafts and the like are commonly delivered using a catheter delivery system. A common type of delivery system for delivering a self-expanding stent is called a pull back delivery system. This type of delivery system utilizes two catheters or shafts which are concentrically arranged, one around another. The stent is carried axially around the distal end of the inner catheter or shaft. The stent is carried to the delivery site on the distal end of the delivery device, held in its compressed delivery position by the outer shaft or catheter. Once at the desired placement site, the outer shaft is pulled back, releasing the stent to self-expand.

In testing, applicant's have observed that the portion of the catheter outside the body is typically not straight, but is curved during pull back. The frictional forces caused by pulling back the outer catheter or shaft cause the curve of the entire device to flatten out, which causes the distal end of the inner shaft or catheter to be urged forward. This undesired forward movement of the inner shaft often leads to inaccurate placement of the stent.

Another factor which can lead to placement inaccuracy are curves inside the body. A common and well known type of delivery is a contralateral insertion approach, where the distal end of the delivery device is placed on the opposite illiac from the original insertion site. In this case, the pull back delivery

systems can also cause the curve placed inside the illiac vessels to straighten out or flatten slightly as the outer catheter or shaft is pulled back. This also causes undesired forward movement of the inner shaft, which can lead to inaccurate placement of the stent.

Schneider's WALLSTENT® product with Unistep™ delivery system utilizes a stainless steel tube as the inner shaft for the portion of the delivery system outside the body, and a plastic flexible tube as the inner shaft inside the body. The stainless steel tube prevents the proximal end of the device from curving outside the body. This device prevents placement error from the curve flattening out outside the body, but does not prevent placement error from a curve flattening out inside the body. Also, the Schneider approach may require different lengths of stainless steel tubing depending on the type of procedure, such as an ipsilateral femoral artery insertion versus a contralateral insertion, or a biliary duct insertion.

There remains a need in the art for a stent delivery system which prevents axial movement of one catheter shaft from causing forward movement of the other catheter shaft, which will allow for accurate placement of a medical device.

Summary of the Invention

The inventive delivery device includes a catheter which is comprised of three concentric shafts. A medical device such as a self-expanding stent is held in a reduced delivery configuration for insertion and transport through a body lumen to a predetermined site for deployment. The stent is carried axially around the inner shaft and is held in its reduced delivery configuration by the middle shaft. An outer shaft is used to stiffen the delivery device so that the arc of the inner shaft will not change outside of the body when the middle shaft is pulled back to release the stent to self-expand. The outer shaft is connected to the inner shaft at the proximal end of the device, which stiffens the delivery system so that the inner shaft will not be urged forward as the middle shaft is pulled backward.

Brief Description of the Drawings

A detailed description of the invention is hereafter described with specific reference being made to the drawings in which:

Figure 1 is a prior art delivery device having two shafts concentrically arranged and with an arc outside the body;

Figure 2 shows the arc outside the body of the prior art delivery device of Figure 1 flattening out as the outer shaft or catheter is pulled back to release the stent;

Figure 3 shows the arc inside the body of a prior art delivery device during a contralateral insertion, with the flattening of the arc during deployment shown in silhouette;

Figure 4 is a sectional view of the inventive delivery system, showing the stent undeployed;

Figure 5 is a sectional view of the inventive delivery system of Figure 3, showing the stent deployed;

Figure 6 schematically shows the arc outside the body of the inventive delivery system with the stent undeployed, and

Figure 7 schematically shows the arc unchanged outside the body of the inventive delivery system with the stent deployed.

Description of the Preferred Embodiments

While this invention may be embodied in many different forms, there are shown in the drawings and described in detail herein specific preferred embodiments of the invention. The present disclosure is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

Figure 1 shows a prior art stent delivery system, shown generally at 10, which is comprised of two concentrically arranged catheters, shafts or manifolds. The inner shaft is shown at 12 and the outer shaft is shown at 14. A medical device such as a self-expanding stent (not shown) is carried axially around the inner shaft 12 and is held in its reduced delivery configuration by the outer shaft 14. The stent is carried near the distal end 16 of the delivery system 10. Reference numeral 18 shows schematically the separation between the portion of the device

which is outside the body and the portion of the device which is inside the body. Reference numeral 20 shows the arc outside the body prior to deployment of the stent.

Figure 2 shows the prior art device of Figure 1 after the outer manifold or shaft has been pulled back to allow the stent to self-expand and deploy. Figure 2 shows that arc 20 has flattened out as the outer shaft 14 is pulled back and inner shaft 12 moves forward.

Figure 3 shows the distal end of a prior art device during a contralateral insertion. As the medical device is deployed, the arc at 22 flattens out from its predeployment position to its deployed position, shown in silhouette at 24.

Referring now to Figures 4 and 5, the inventive deployment system is shown schematically and generally referred to as 30. The outer stiffening shaft is referred to at 32, the middle pull back shaft is referred to at 34 and the inner shaft is referred to at 36. The inner shaft 36 can function as the lumen for a guide wire. A medical device, such as self-expanding stent 38 is shown in the delivery position in Figure 4, carried axially around inner shaft 36 and held in its reduced delivery configuration by middle pull back shaft 34. The outer shaft 32 and inner shaft 36 are connected together by manifold stabilizer 40 at the proximal end of the device. It is important that the two shafts are connected together far enough apart to provide enough room for the middle pull back shaft to be fully retracted to completely release the stent 38 to self-expand, as shown in Figure 5. By connecting the outer shaft 32 and the inner shaft 36 with manifold stabilizer 40, the inner shaft 36 is held in position during pull back of the middle pull back shaft 34, thereby preventing any flattening of the outside the body arc or the inside the body arc during deployment. The inventive delivery system provides for accurate placement of the medical device.

Referring now to Figures 6 and 7, the inventive delivery device 30 is shown prior to deployment and after deployment. Figure 7 shows that the manifold stabilizer 40 prevents any flattening of arc 20 as middle pull back shaft 34 is retracted to allow the stent 38 to self-expand (shown in Figure 5). Similarly, the inventive delivery device will prevent any flattening of the arc inside the body, shown in Figure 3, during a contralateral insertion.

This completes the description of the preferred and alternate embodiments of the invention. It is to be understood that even though numerous characteristics and advantages of the present invention have been set forth in the foregoing description, together with the details of the structure and function of the invention, the disclosure is illustrative only and changes may be made in detail, especially in matters of shape, size and arrangement of parts within the principals of the invention, to the full extent indicated by the broad, general meaning of the terms in which the appended claims are expressed. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which are intended to be encompassed by the claims attached hereto.

WHAT IS CLAIMED IS:

1. A delivery system for implantation of a medical device in a vessel, comprising:

elongate flexible catheter means having proximal and distal ends for delivering a medical device to a predetermined location in a vessel of a patient, the elongate flexible catheter means being further comprised of:

an inner shaft which carries the medical device near its distal end,

a middle pull back shaft concentrically arranged around the inner shaft, the medical device being carried between the inner shaft and middle pull back shaft, and

an outer stiffening shaft concentrically arranged around the middle pull back shaft, the inner and outer shafts being connected at their proximal ends to prevent axial movement of the inner shaft with respect to the outer shaft,

whereby the medical device is delivered at the desired site by pulling on the proximal end of the middle pull back shaft, which deploys the medical device, and where the outer stiffening shaft connection to the inner shaft prevents axial movement of the inner shaft with respect to the outer stiffening shaft, thereby preventing the distal end of the inner shaft from being urged forward during delivery and therefore allowing for more accurate placement of the medical device.

2. The delivery system of claim 1 wherein the inner and outer shafts are connected together far enough apart to allow the middle pull back shaft to retract a distance at least as great as the axial length of the medical device to be delivered.

3. The delivery system of claim 1 wherein the inner shaft provides a lumen for a guide wire.

4. The delivery system of claim 1 wherein the medical device is a self-expanding stent.

5. A method of delivering a medical device using the delivery system of claim 1, comprising the steps of:

moving the distal end of the elongate flexible catheter means to a delivery site, and

delivering the medical device by pulling back on the middle pull back shaft which releases the medical device,

whereby the outer stiffening shaft connection to the inner shaft prevents the distal end of the inner shaft from being urged forward as the middle pull back shaft is retracted, thereby allowing for more accurate placement of the medical device.

Fig. 1

PRIOR ART

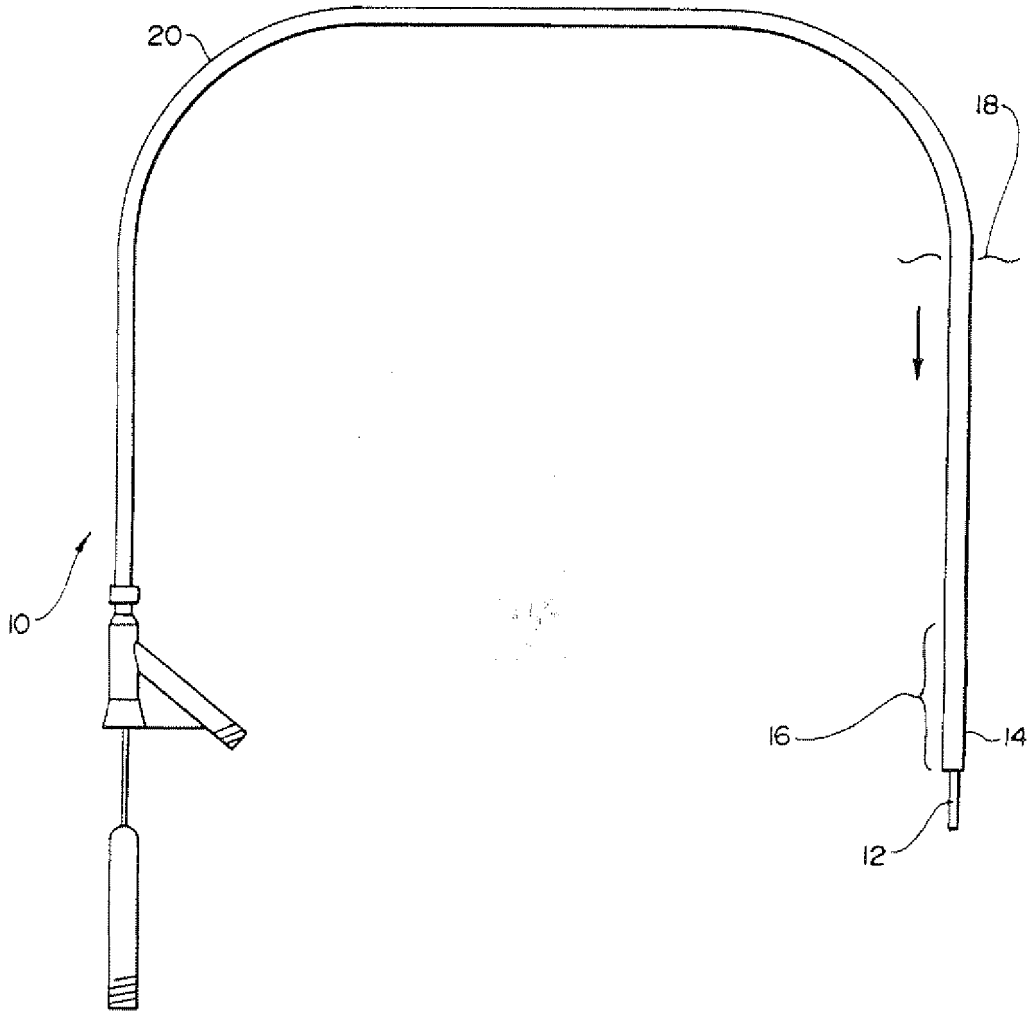
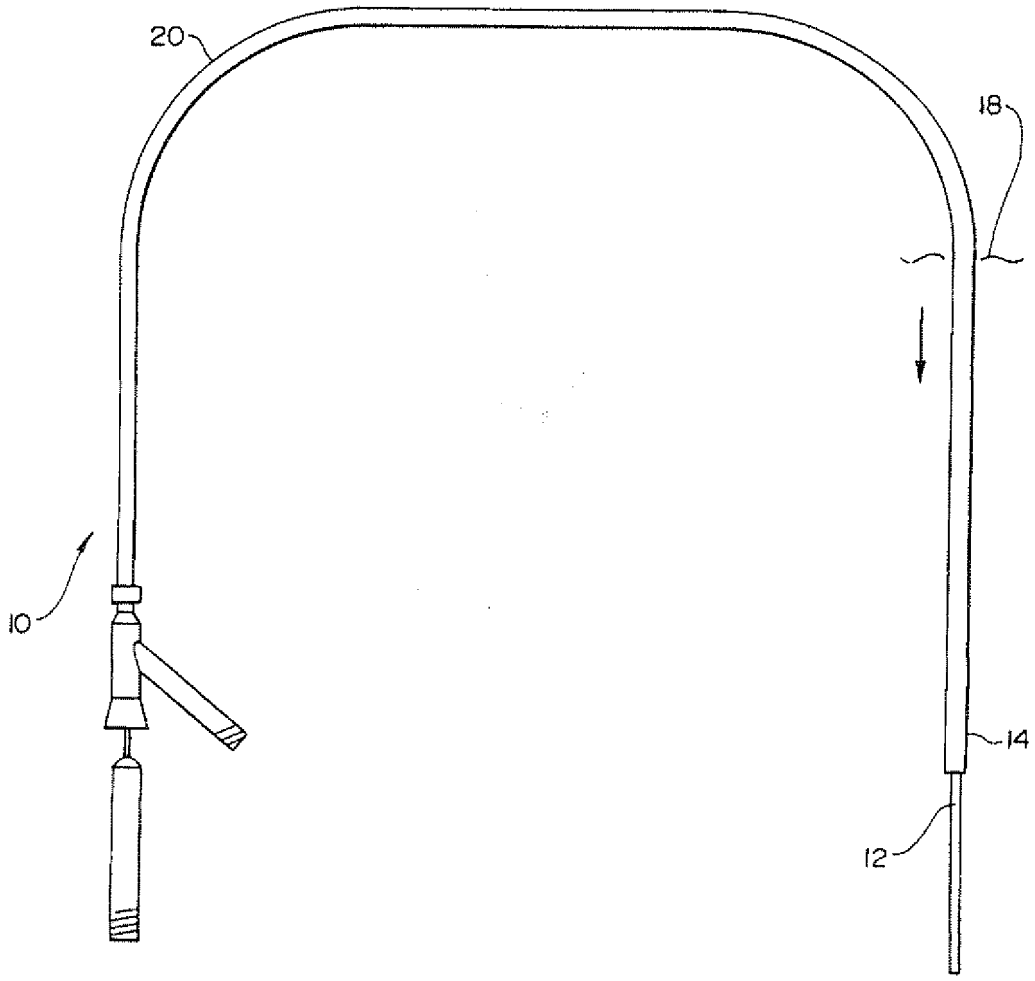


Fig. 2

PRIOR ART



3/6

Fig. 3

PRIOR ART

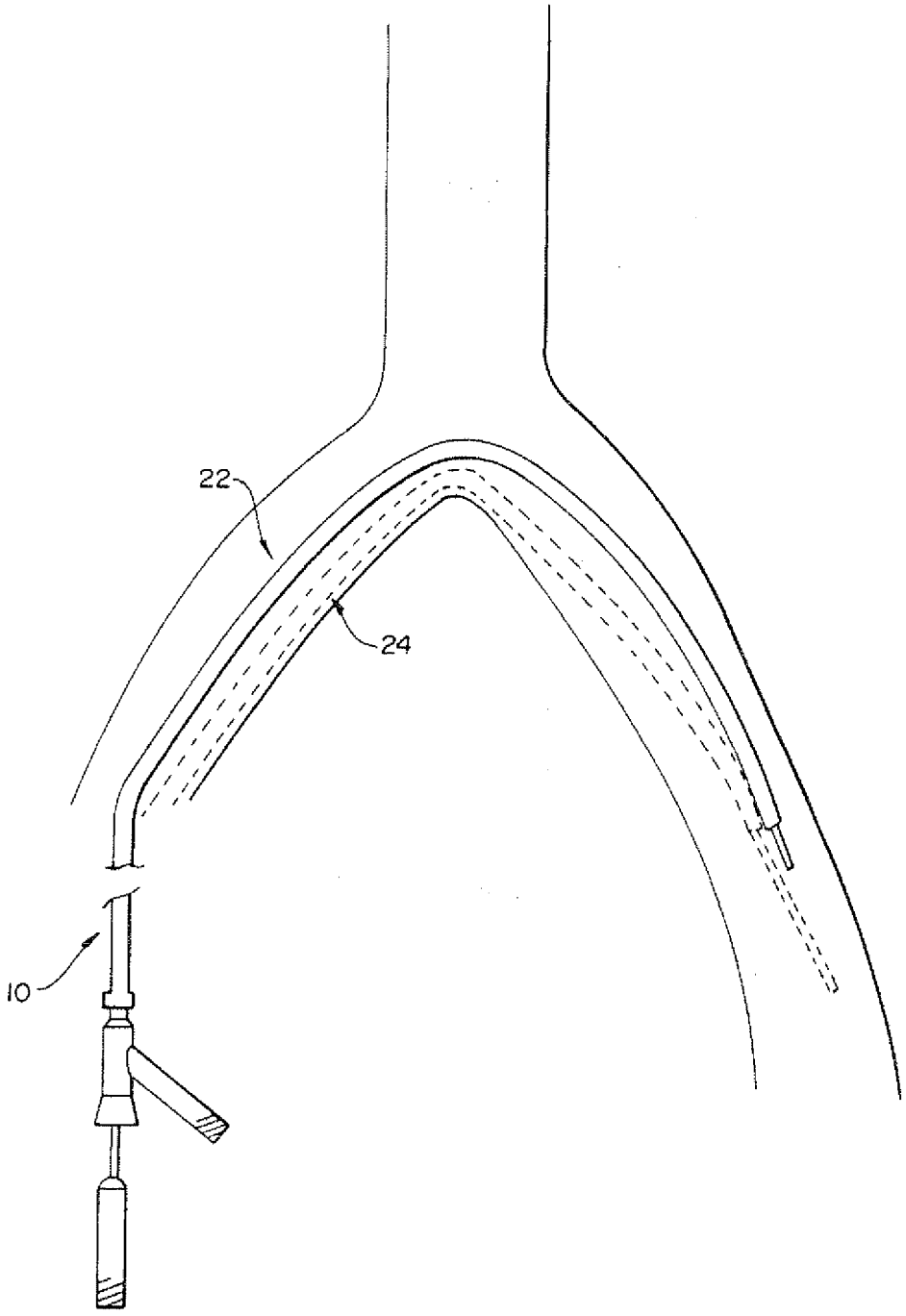


Fig. 4

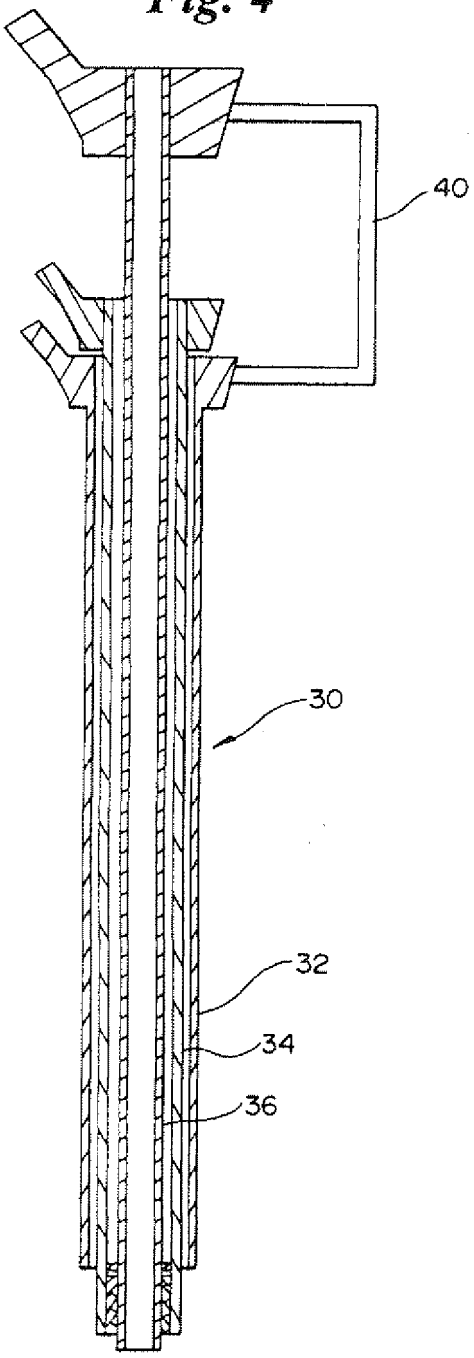


Fig. 5

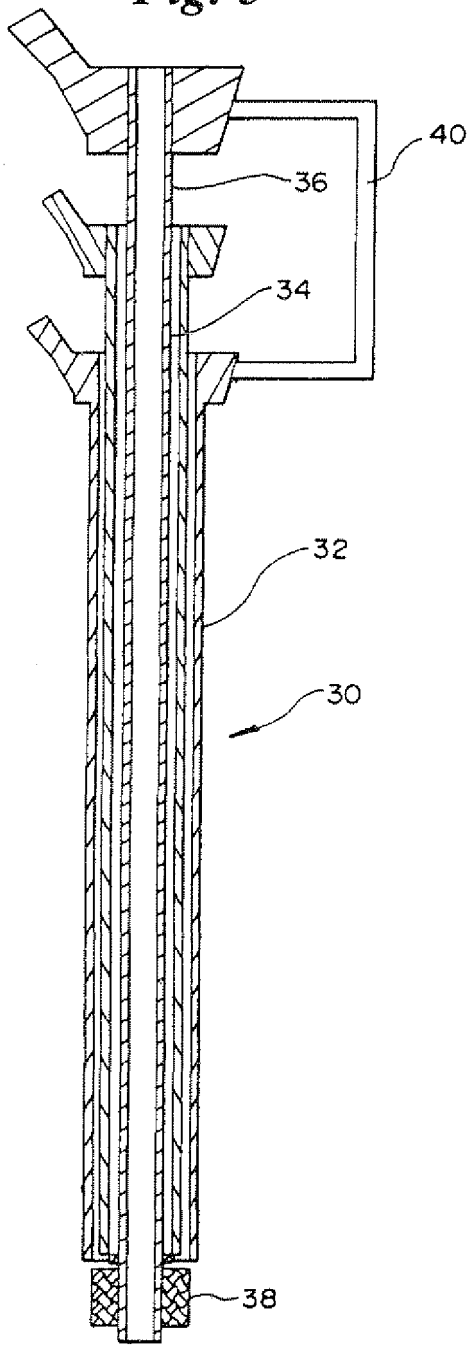


Fig. 6

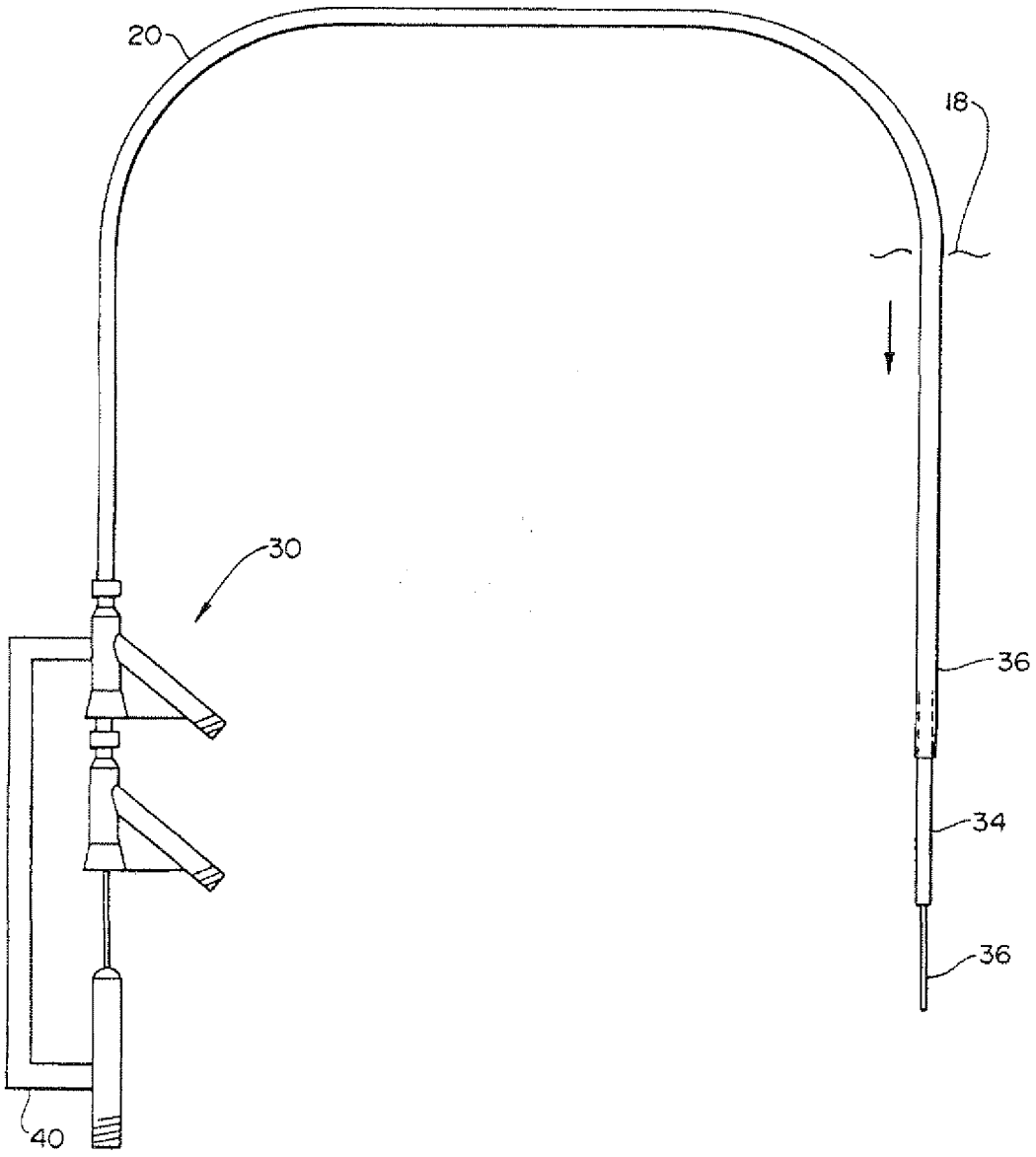
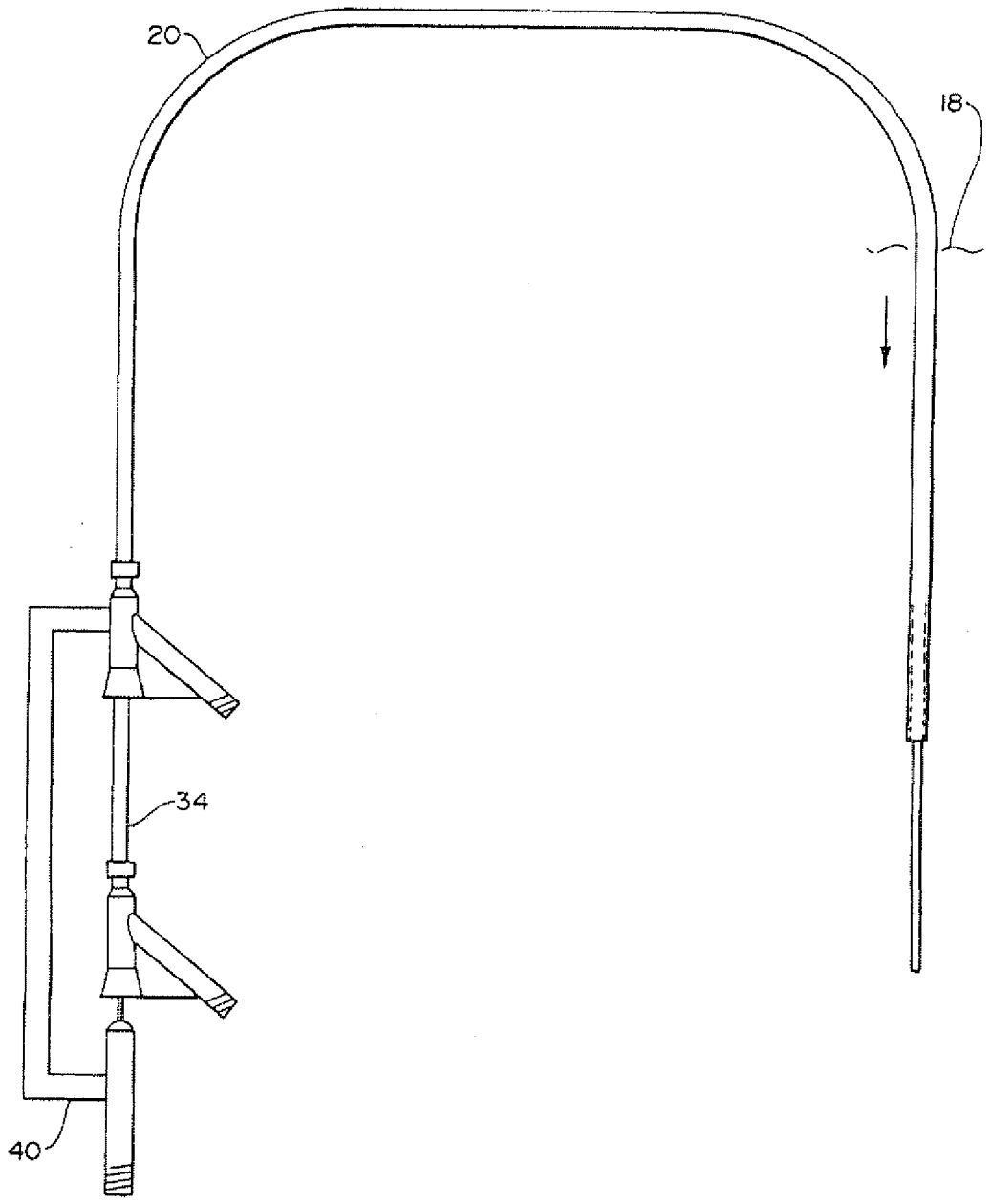


Fig. 7



INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 96/04744

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,4 665 918 (GARZA ET AL.) 19 May 1987 see column 5, line 31 - line 56; figure 12B	1-4
X	US,A,5 201 757 (HEYN ET AL.) 13 April 1993 see column 5, line 24 - column 6, line 35; figures 1-3	1,3,4
A	EP,A,0 627 201 (SCHNEIDER (EUROPE) AG) 7 December 1994 see column 3, line 1-55; figures 1-4	1-4

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

2

Date of the actual completion of the international search	Date of mailing of the international search report
11 July 1996	09.08.96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Ehrsam, F

Form PCT/ISA/210 (second sheet) (July 1992)

ernational application No.

PCT/US96/04744

INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 5
because they relate to subject matter not required to be searched by this Authority, namely:

Consists of a method of treatment of the human body.
See Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No
PCT/US 96/04744

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4665918	19-05-87	NONE		
US-A-5201757	13-04-93	AU-B-	3722393	08-11-93
		CA-A,C	2132018	14-10-93
		DE-U-	9390077	01-12-94
		EP-A-	0633756	18-01-95
		JP-T-	7501476	16-02-95
		WO-A-	9319703	14-10-93
EP-A-627201	07-12-94	AU-B-	659975	01-06-95
		AU-B-	6343794	15-12-94
		JP-A-	7051384	28-02-95

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06 — A1

(11) International Publication Number: WO 96/31174

(43) International Publication Date: 10 October 1996 (10.10.96)

(21) International Application Number: PCT/US96/04744

(22) International Filing Date: 5 April 1996 (05.04.96)

(30) Priority Data:
08/417,385 5 April 1995 (05.04.95) US

(71) Applicant: SCIMED LIFE SYSTEMS INC. [US/US]; One Scimed Place, Maple Grove, MN 55311-1566 (US).

(72) Inventor: DEL TORO, Connie; 2165 H Shenandoah Court, Plymouth, MN 55447 (US).

(74) Agents: ANDERSON, William, E., II et al.; Vidas Arrett & Steinkraus, Suite 1540, 920 Second Avenue South, Minneapolis, MN 55402-4014 (US).

(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

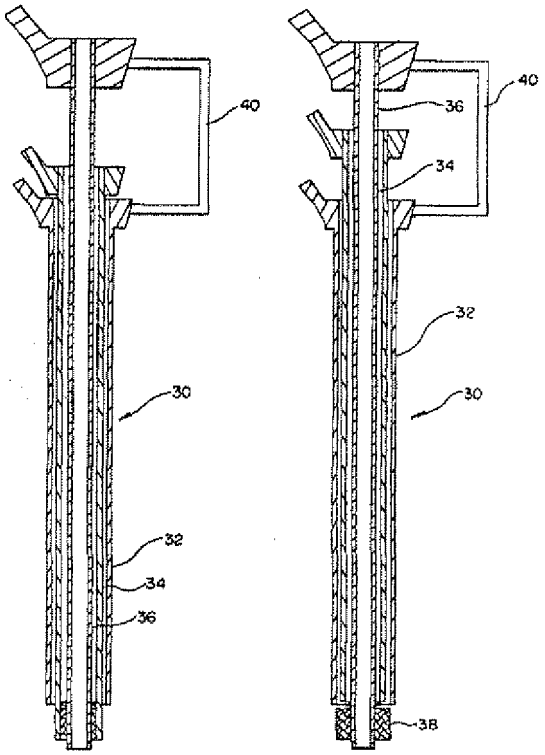
Published
With international search report.
With amended claims.

Date of publication of the amended claims:
21 November 1996 (21.11.96)

(54) Title: PULL BACK STENT DELIVERY SYSTEM

(57) Abstract

A delivery system (30) for implantation of a medical device in a vessel which has three concentric shafts (32, 34, 36), an inner shaft (36) for carrying a medical device (38), a middle pull back shaft (34) and an outer stiffening shaft (32). The inner and outer shafts are connected together at the proximal end (40) of the delivery system to preclude the inner shaft from moving axially relative to the outer shaft as the middle pull back shaft is retracted. This allows for accurate placement of the medical device.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

AMENDED CLAIMS

[received by the International Bureau on 9 October 1996 (09.10.96);
original claims 1 and 5 amended; new claim 6 added;
remaining claims unchanged (2 pages)]

1. A delivery system for implantation of a medical device in a vessel, comprising:

a medical device; and

elongate flexible catheter means having proximal and distal ends for delivering a medical device to a predetermined location in a vessel of a patient, the elongate flexible catheter means being further comprised of:

an inner shaft which carries the medical device near its distal end,

a middle pull back shaft concentrically arranged around the inner shaft, the medical device being carried between the inner shaft and middle pull back shaft, and

an outer stiffening shaft concentrically arranged around the middle pull back shaft, the inner and outer shafts being connected at their proximal ends to prevent axial movement of the inner shaft with respect to the outer shaft,

whereby the medical device is delivered at the desired site by pulling on the proximal end of the middle pull back shaft, which deploys the medical device, and where the outer stiffening shaft connection to the inner shaft prevents axial movement of the inner shaft with respect to the outer stiffening shaft, thereby preventing the distal end of the inner shaft from being urged forward during delivery and therefore allowing for more accurate placement of the medical device.

2. The delivery system of claim 1 wherein the inner and outer shafts are connected together far enough apart to allow the middle pull back shaft to retract a distance at least as great as the axial length of the medical device to be delivered.

3. The delivery system of claim 1 wherein the inner shaft provides a lumen for a guide wire.

4. The delivery system of claim 1 wherein the medical device is a self-expanding stent.

5. A method of delivering a medical device using the delivery system of claim 1, comprising the steps of:

providing the delivery system of claim 1;

moving the distal end of the elongate flexible catheter means to a delivery site; and

delivering the medical device by pulling back on the middle pull back shaft which releases the medical device,

whereby the outer stiffening shaft connection to the inner shaft prevents the distal end of the inner shaft from being urged forward as the middle pull back shaft is retracted, thereby allowing for more accurate placement of the medical device.

6. A delivery system for implantation of a medical device in a vessel, comprising:

an elongate flexible catheter means having proximal and distal ends for delivering a medical device to a predetermined location in a vessel of a patient, the elongate flexible catheter means being further comprised of:

an inner shaft;

a middle pull back shaft concentrically arranged around the inner shaft, whereby the medical device may be carried between the inner shaft and middle pull back shaft; and

an outer stiffening shaft concentrically arranged around the middle pull back shaft, the inner and outer shafts being connected to prevent axial movement of the inner shaft with respect to the outer shaft,

wherein the middle pull back shaft is retractable relative to the inner shaft and the stiffening shaft by pulling on the proximal end of the middle pull back shaft, and wherein the outer stiffening shaft connection to the inner shaft prevents axial movement of the inner shaft with respect to the outer stiffening shaft.